

Subject: Detection of Non-Endotoxin Pyrogens  
Date: Tuesday, June 7, 2011 11:19 AM  
From: Hoffmeister, Alan

Dear Dr. Casey,

I read the recent article on the Detection of Non-Endotoxin Pyrogens with interest. I was surprised to see that five in-vitro test methods were being considered, for use to detect Gram-negative endotoxin in human parenteral drugs, as a replacement for the RPT, when the LAL based BET is universally accepted as the Gram-negative endotoxin test of choice. Can you confirm whether or not these test methods are being proposed as a replacement for the LAL based BET and if so on what basis?

Also, could you give details of which non-endotoxin pyrogens (standards or otherwise) will be used in the evaluation of the MAT methods, in the proposed additional validation studies to evaluate their usefulness for identifying non-endotoxin pyrogens?

Best regards,

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